

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

President Stanton Ades called the public meeting to order at 8:44 A.M.

In attendance were President Stanton Ades, Commissioners: W. Irving Lottier, Wayne Dyke, Ramona McCarthy Hawkins, Melvin Rubin, Barbara Faltz Jackson, Jeanne Furman, Laura Schneider, David Russo, Donald Yee, and Rev. William Johnson; Board Counsel, Paul Ballard; Board Staff, Executive Director, Norene Pease; PCO, Michelle Andoll and Secretary, Wendy Wilson, and PEP Student, Melanie O'Banian.

Commissioner absent was: Raymond Love

Guests present: Ralph Progar, Neil Smith, Phil Cogan, Mike Nicholson, Robert Vlk, Donna Mazyck, Michael Johansen, Nathan Gruz, Mark DiMaio, and Cathy Putz.

Recusals -

President Ades requested that any member of the Board with a conflict of interest relating to an item on the agenda should notify the Board at this time.

Mr. Dyke was recused from the discussion of PCS/Rite Aid since PCS mail-order is a subsidiary of Rite Aid Corporation.

Approval of Minutes -

Page eight (8) under Public Relations Committee, paragraph two should read, “ Ms. Faltz Jackson stated that the Committee wants to launch a program to educate consumers about how, as a team, well informed consumers and pharmacists can reduce the occurrence of medication errors.” Page eight (8) under Peer Review, Ms. Furman suggested that both pharmacists and establishment permit holders should receive the Board’s list of suggestions on how to reduce medication errors.

A motion was made by Ms. Furman to approve the July 21, 1999, minutes as amended. Ms. Hawkins seconded the motion, with a unanimous decision from the Board.

President Ades introduced the Board’s new Pharmacist Compliance Officer, Michelle Andoll.

Executive Director's Report/Executive Committee Report

Bimonthly Report to the Secretary DHMH -

Ms. Pease reported that the Board has received approval for the request for proposal (RFP) for the Media Campaign contract to be released to the public for responses.

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

Internet Pharmacy -

Representatives from the Joint Task Force on Internet Medicine and Pharmacy met with the U.S. Commerce Committee on July 23, 1999. The National Committee wanted to meet with a State that is addressing *Internet* prescribing and dispensing issues. Representatives from the Board of Physician Quality Assurance (BPQA), Pharmacy and the Office of the Assistant Attorney General met with Congressional staff members.

Spring Grove -

Mr. Rubin and Ms. Cornish (Licensing Supervisor) attended a meeting on the move to Spring Grove with Robert Beasman and Richard Proctor. Representatives from several of the Boards were also present. Mr. Rubin reported that a decision has been made by the Department regarding the Board of Pharmacy which will not be moving to Spring Grove. Rather, the Board will be given the opportunity to expand its offices at the present location to accommodate its staff. The Board has been given a substantial amount of space for this expansion and needs to reevaluate space requirements and devise a plan.

Ms. Pease reported that there will be an Executive Officers Conference that will take place on September 26-29, 1999 in Washington, DC. This is considered an in-state trip, and if any member of the Board would be interested in attending, there is money in the budget to cover the cost of registration and travel to and from the conference. This is not to include the hotel stay. President Ades stated that he has already signed up for this conference.

Guest Presenter - Melanie O'Banian (Accomplishing Glucose Monitoring In Other States - CLIA Regulations) - Board student for the month -

Ms. O'Banian researched whether a pharmacist in the State of Maryland could be authorized to perform laboratory tests. Ms. O'Banian referred the Board to the Maryland Register-10.10.03.01(a) where it states that a person shall possess a license before: offering or performing a medical laboratory test or examination in this State. Ms. O'Banian put together a commentary from several other states which allow pharmacists to perform laboratory tests, including: North Carolina where pharmacists are successfully monitoring diabetes by taking blood glucose levels; Ohio where there is currently no law that permits or prevents a pharmacist from performing lab tests; Texas, where as long as the pharmacist complies with all of the legal requirements specific for each type of test, utilization of invasive procedures to monitor a patient is permitted; Virginia, where collaborative practice legislation was recently enacted for pharmacists. The task of performing laboratory tests can now be delegated to pharmacists under this new legislation;

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

Florida, where a pharmacist who has been licensed as a consultant pharmacist in the State is permitted to perform laboratory testing.

Ms. O'Banian reported that there were several states that prohibit laboratory testing by pharmacists, including Massachusetts, New York, New Jersey, New Hampshire, Vermont and Connecticut. In conclusion, Ms. O'Banian stated that she felt that Maryland should be included in the states that allow laboratory testing, and that the Board should move forward on this issue to seek interpretation of current regulations such that a pharmacist may perform such testing.

Ms. Pease stated that the comment period for the CLIA Regulations is over. Ms. Pease suggested referring the CLIA issue to Mr. George Voxakis' group to consider along with collaborative practice.

Mr. Yee suggested limiting the Board's involvement to avoid potential conflicts with laboratory directors and laboratories who profit from these tests. Ms. Furman stated that there are currently pharmacists who are performing these type of tests under direct order from doctors.

Board Counsel's Report - None

Committee Reports

Licensing Committee - Wayne Dyke

Mr. Dyke reported that there were eighteen (18) candidates for the reciprocity meeting held on August 17, 1999. The candidates were as follows: John Boeth, Marcia Catalano, Neil Etwaroo, Kenneth Ginsburg, Jarrod Hazlett, Elaine Hu, Brent Kelly, Elizabeth Kidane, Craig Kiester, Janice Lopez, Susan McCaughan, Tara Neil, Brenda Raffath, Jennifer Reese, Sharon Sandman, Gregory Sosnowski and Kelly Whitlow. Mr. Dyke moved that all reciprocity candidates be approved with the exception of Kenneth Ginsburg who needed to complete the oral competency examination and would be licensed once the oral competency has been approved. The motion was seconded by Ms. Jackson, with a unanimous decision from the Board.

Mr. Dyke reported that there was a licensing committee meeting that was held on August 10, 1999. One hundred and thirty-nine (139) candidates passed the NAPLEX examination, with only ten (10) failures. One hundred and seventy-two (172) candidates took the laboratory examination, with only two (2) failures, and approximately thirty (30) candidates are waiting for results from the MPJE examination, where there have been a total of seven (7) failures.

Mr. Dyke reported that the date for the Fall examination will be Tuesday, October 12, 1999 and will be held at the School of Pharmacy. Mr. Dyke stated that the Board will need proctors to

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

volunteer. The first Winter offering for the wet laboratory examination will be either January or February 2000, and as soon as the date is secured a letter will go out to the pharmacy school. Mr. Dyke stated that there were discussions on proctoring the laboratory examination. It was agreed that some changes needs to be made. One change was that proctors would be given a protocol for how to handle various questions and situations that arise during the course of giving the examination.

Mr. Dyke reported that the committee discussed how to handle stores undergoing renovations and emergencies as a result of fire, storms, etc., where an establishment would seek approval for a temporary site for the continued operation of a pharmacy. Mr. Dyke stated that currently, there is no regulation for such situations and will work with the Licensing Committee to draft proposed policy. Mr. Dyke requested that staff obtain other state laws regarding this issue.

Waiver Pharmacies -

Mr. Dyke stated that there should be changes made to the pharmacy waiver approval process. Mr. Dyke suggested that categories be placed on the application, one which would specify why a licensee would require a waiver permit. Ms. O'Banian, who reviewed how waivers are granted in Maryland and in other States, stated that categories for types of waivers should be established. Mr. Rubin stated that the Board currently has two (2) types of pharmacy applications, full service pharmacies and restricted services (waiver). Mr. Rubin agreed that the Board should establish approved categories for waivers.

Ms. Schneider stated that the applicants have been neglecting to fill out section four (4) of the waiver application which states: *explain the specialized settings (such as equipment, systems, location, or physical structure) applicant will use that is usually present in a pharmacy*. Ms. Schneider stated that this section should be filled out so that the Board will have in its record the types of equipment necessary for the establishment to operate effectively in its business.

The Licensing Committee agreed to take Ms. O'Banian's report and make final recommendations for categories for waivers and changes to the waiver application that would enable the Board Secretary and Board staff to make informed decisions when approving waiver requests. Secretary Lottier will review the recommended changes to the waiver application that are developed by the Licensing Committee.

Regulation Update -

Prehearing Procedures to be added to Chapter 01 Formal Hearings.

Mr. Ballard stated that these provisions are routine and that they are in all the Boards regulations.

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

President Ades asked if the Board wanted to change any of the language. Mr. Ballard stated that the language seemed appropriate, and there is no need for any change. A quorum of the Board agreed to add a prehearing component to these regulations. Ms. Jackson motioned to accept the language on prehearings as follows, “ All motions shall be accompanied by a memorandum of points and authorities and shall be filed with the Board at least 15 working days before the hearing and a copy served on the opposing party. A response shall be filed with the Board at least 10 working days before the hearing and a copy served on the opposing party.” Ms. Hawkins seconded the motion, with a unanimous decision from the Board.

Ms. Pease stated that the Board’s new Legislative Officer, Anil Punyapu was supposed to start work on August 17, 1999, but one of his family members was ill.

Notice of Final Action Pharmacist Code of Conduct -

Ms. Pease stated that these regulations have become final and that each Board member should keep a copy of these regulations that was published in Maryland Register in their law book.

COMAR 10.34.16 (Portable Drug Kits for Licensed Home Health Agencies and Hospices)

Ms. Pease stated that these regulations are undergoing comment period. Ms. Pease stated that she did receive one comment from Nick Lykos who was speaking on behalf of MPHA. Mr. Lyko’s comment was whether or not the Board needs to put something in regulations that would determine the location where the particular drugs might be stored, for example, in a home health agency there are lots of places where these drugs can be stored.

Mr. Yee stated that since the Board does not specifically identify where drugs will be appropriately stored, the Board may therefore, make decisions on a case by case basis. Mr. Ballard stated that he feels that storage of drugs warrants exercising the professional judgement of the health professional who is responsible for their safe and appropriate keeping. Mr. Rubin stated that the Board may want to strengthen the language in these regulations (10.34.16.04 .04 Requirements of the Portable Drug Kit (f) to state, “Storage requirements for the stability of the contents.”

Ms. Hawkins motioned to amend 10.34.16.04 04(f) as recommended by Mr. Rubin. Ms. Jackson seconded the motion, with a unanimous decision from the Board.

Discovery Regulations -

Ms. Jackson motioned to accept the regulations as provided in the August Board Packet as written. The motion was seconded by Ms. Hawkins, with a unanimous decision from the Board.

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

Comments on Security Regulations -

Pharmacy Security Regulation revisions were published in the Maryland Register on July 2, 1999. Mr. Dyke asked that the Board consider changing the language in these regulations which state: *10.34.05.02(b)- prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open.* Mr. Dyke stated that questions had been raised regarding the need for a physical barrier. Mr. Dyke asked if the Board would consider language allowing recognized management individuals in the store, perhaps a certified list of individuals who had undergone additional background checks to have access to the pharmacy. Mr. Dyke further stated that the current language does not allow any room for internal or external security investigations. Board members noted that security investigations could be conducted in the presence of any licensed pharmacist. Board guest and former National Association of Boards of Pharmacy President, Mr. Progar stated that he is concerned about the suggestion of a list of certified individuals (non pharmacists). Mr. Russo stated that the pharmacy(s) needs to have protocol in place for such situations.

Mr. Dyke also suggested that section .04 Records was too stringent implying that pharmacies must provide to the Board a list of persons authorized to have access to patient records. The regulation is not restrictive and only implies that the pharmacy must always know who has access to patients records in the event that such information would be requested or subpoenaed by the Board or another entity with similar authority.

Mr. Russo motioned to leave the regulations as proposed and not entertain any changes. The motion was seconded by Ms. Jackson, with a unanimous decision from the Board.

Regulations Status Report - July 1999 -

Ms. Pease stated that she will ask the Board's new Legislative Officer, Anil Punyapu to continue to maintain a regulations tracking system and make monthly status reports to the Board.

PEAC (Pharmacists Education and Assistance Committee) Update -

Mr. Rubin reported that he will meet with PEAC representatives on August 19, 1999. Mr. Rubin stated that the Board hopes to have a two way computer electronic transmission with PEAC operable in the fall.

Pharmacy Practice Committee -

Ms. Andoll reported that the Pharmacy Practice Committee met on August 4, 1999. Ms. Andoll stated that there were several concerns about internet prescribing and dispensing discussed at this

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

meeting, which were: lack of patient relationship/patient confidentiality, lack of physical traces of pharmacy, copy cat drugs and adulterated products. Ms. Andoll stated that Congress has been looking into having the state license every internet pharmacy. Ms. Andoll stated that the best way to safeguard the public with their concerns is to educate them.

Y2K Statement -

Ms. Andoll reported that Dr. Love distributed a draft Y2K statement which is geared toward the public and is intended to be part of the Board's education initiative. Mr. Rubin suggest that this statement be made available in the public libraries, pharmacies, etc. Mr. Lottier stated that he has drafted of an article that will be placed in the Board's newsletter that will also address the Y2K concerns and how to be ready for them. The newsletter will be published in October 1999. Ms. Jackson motioned to accept in concept the Y2K article and have it edited by staff and reviewed by the DHMH Public Relations Office prior to its release. Ms. Hawkins motioned to amend the last section of article under "what is the Board of Pharmacy doing to make sure that my pharmacy is ready for Y2K", third (3) paragraph, to delete the word other. The motion was seconded by Mr. Yee as amended, with a unanimous decision from the Board.

Code of Conduct - Conscience Clause for Emergency Contraception and MACDS Recommendations -

Ms. Andoll stated that the committee reviewed the MPHA Conscience Clause. There was a lengthy discussion about the pros and cons of placing a conscience clause into regulations as part of the Code of Conduct. President Ades suggested setting up a committee to come up with a uniform agreement for a response to consumers and to pharmacists for a standard answer for questions that would be presented to the Board regarding this issue. The Committee should also recommend if such a statement should be promulgated as a revision to the Code of Conduct Regulations. Ms. Schneider, Mr. Dyke, Rev. Johnson and Mr. Yee agreed to participate on this committee.

Compounding for Drug Study, Labeling without Patient Name -

Ms. Andoll stated that a request was made for compounded products for a drug study be labeled with a number for each patient instead of the patient's name in order to maintain patient confidentiality. The Practice Committee found this to be acceptable. Dr. Love stated that he would contact the pharmacist involved with the study to write procedures for the drug preparation and labeling and submit those procedures to the Board for approval.

Review of Confidentiality Issues Including Refill Reminders -

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

Ms. Andoll stated that the Committee agreed that the Board needed regulations to address refill reminder programs that will assure the protection of patient confidentiality. The Committee will continue discussing this to prepare draft regulations for the Board to review.

Regular Regulatory Review: 10.13.01, 10.13.04, 10.13.08 -

Dispensing of Prescriptions by a Licensee - 10.13.01 Ms. Andoll stated that the practice committee saw no need for changes to this regulation. The Board concurred that no changes were needed.

Label of Prescription for Drugs (Other than Narcotic Drugs) That May be Dispensed Only Upon Prescription 10.13.04 -

Ms. Andoll stated that the entire regulation is obsolete and should be eliminated. Ms. Furman motioned to strike Chapter 4 from regulations. The motions was seconded by Ms. Hawkins, with an unanimous decision from the Board.

Sale of Needles and Syringes or Other Paraphernalia - 10.13.08

Ms. Andoll reported that the Committee recommended no changes. There was discussion concerning whether or not the sale of syringes should be regulated by the Board when sold in pharmacies since syringes are available in other unregulated settings. Ms. Furman motioned to delete - "The record of sale shall be recorded in a registry to be established for this purpose which shall contain the purchaser's name and address, date of sale, item and quantity sold, and the signature of the pharmacist," from these regulations. The motion was seconded by Mr. Yee, with a unanimous decision from the Board. Ms. Jackson abstained from the vote.

Medication Administration in Schools - Meeting August 10th -

On August 10, 1999, Donna Mazyck, Vicki Taliaferro (MSDE), Pamela Putman (DHMH), Barbara Newman (Board of Nursing), Jeanne Furman, Rev. Johnson and Mr. Rubin met to discuss the administration of medication to students when attending field trips. Ms. Furman stated that the issue is not the administration but the labeling of the medication and who is allowed to dispense. Currently, MSDE (Maryland State Department of Education) has a policy which will allow school nurses to delegate the administration of medication to the teacher who is in charge of the students on the field trip. Ms. Mazyck stated that the safety standards in place have been successful for the past eight (8) years and that MSDE would like to keep the current policy. Ms. Furman motioned to accept MSDE's recommendation with modifications concerning how emergency is defined which would have the effect of limiting the types of medications that would be administered to children when on field trips. The motion was seconded by Rev.

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

Johnson, with a unanimous decision from the Board. Ms. Jackson abstained from this decision.

Automation Task Force -

Ms. Furman stated that she had an inquiry about automated medication dispensing machines utilized in sub-acute units of facilities otherwise licensed as hospitals. Ms. Furman stated that she received a call from Washington County Hospital asking why DDC told them that they can not have medication dispensing servicing sub-acute patient units. Ms. Furman reported that the Board is currently writing regulations to address this concern and will be meeting with DDC and Licensing and Certification to modify automated dispensing regulations in alternative sites. The Board wants to be very specific on how they want these machines to be monitored and when they are used.

Public Relations Committee/Counsel of Boards Report -

Ms. Jackson stated that a meeting to review responses to the media campaign request for proposals will take place in September 1999. Ms. Banks reported that a question arose regarding the raising of funds for the campaign which is an element in the RFP. Mr. Ballard stated that under state law if a person or entity is not registered as a fund raising organization, it would be a violation of law to be involved in fund raising activities. Ms. Banks stated that in order to raise funds, individuals or entities must register with the state. This law became effective in July 1999.

Ms. Banks stated that the Committee has received a list of all vendors that have requested copies of the RFP. The vendors will have until August 31, 1999 to submit their proposals. Ms. Pease asked for Board members to volunteer to read and evaluate proposals once they are received. This would require approximately three (3) meetings. Ms. Banks stated that the proposals are at least sixty (60) pages each. Mr. Yee and Mr. Rubin volunteered to assist in the reading of the proposals. Ms. Jackson motioned to remove the fund raising section from the RFP. The motion was seconded by Mr. Yee, with a unanimous decision from the Board.

Disciplinary Committee -

Mr. Rubin reported that Ms. Levi drafted an educational tool to remind pharmacists and consumers about steps that can be taken to reduce the incidence of medication errors. President Ades suggested changing the introduction of the medication error education sheet to say, "Recommendations that may help assist in avoiding medication errors." The educational materials should place additional focus on reducing the incidence of medication errors for children and the elderly.

Mr. Rubin stated that Ms. Schneider will come in to review disciplinary cases on Thursday,

The Maryland Board of Pharmacy Public Minutes - August 18, 1999

August 26, 1999, at 2:00 p.m.

Peer Review - Medication Error Prevention Project -

Mr. Yee is currently soliciting for members to join this Task Force. Mr. Yee stated that Mr. Steele (Board student) did some research on what other states are doing to prevent these types of errors. Mr. Yee will report on the composition of the Task Force and its work plan at a future meeting.

Budget Committee - F.Y.99 Year End Report - Tamarra Banks -

Ms. Banks presented to the Board a fiscal report (June 1, 1998 to July 1, 1999) for 1999 budget and revenue activity. There were no reported areas of concern. Ms. Banks is preparing the F.Y. 2001 budget and will present it to the Board for approval in September.

Questions for the Board

New Inquiries -

PCS/Rite Aid: PCS Prescriptions directed to Rite Aid pharmacy -

Mr. Rubin reported that PCS, a mail order service owned by Rite Aid, fell behind in filing prescription orders due to a relocation of their establishment. The Board would like to make sure PCS is accommodating its patients with alternative ways of receiving their medication in a timely manner. PCS currently has a Short Term Request Policy which states, "When a patient is in need of a local supply of medication, PCS allows the patient to obtain a thirty (30) day supply at the pharmacy of their choice. This offer should be provided to the member when their order has been in house over eight (8) days."

PDX Prescription Transfer System -

Ms. Andoll stated that Wal-Mart made a request to the Board for using PDX computer software systems. This system will allow automatic transfer of prescriptions between both in-state and out-of-state Walmart Stores. This system will only be used for non-controlled prescriptions. Mr. Rubin motioned to approve this system. Ms. Jackson seconded the motion, with a unanimous decision from the Board. Ms. Pease will draft a letter to Wal-Mart letting them know of the Board's decision.

Informational - none

**The Maryland Board of Pharmacy
Public Minutes - August 18, 1999**

Follow - Up Letters/Meetings - none

The meeting was adjourned by President Ades at 12:30 p.m.

Respectively Submitted,

W. Irving Lottier, Jr.
Secretary